

Application No. 09/384,900

REMARKS

In the current Office Action of May 19, 2003, the previous rejection based primarily on United States Patent 5,919,163 to Glickman (hereafter "Glickman patent") has been renewed. As is explained below, reliance on the Glickman patent is misplaced because it directly teaches away from the present invention as claimed. Reconsideration and withdrawal of the rejections based upon the Glickman patent are respectfully requested.

In the present application claim 24 (previously amended) specifically defines a unique structure of a sleeve that is adapted to be attached to a catheter shaft in order to create a catheter balloon. In particular, the claim reads as follows:

24. (previously amended) A sleeve adapted to be mounted on a catheter shaft so as to be formed into an inflatable balloon comprising
the sleeve having a first end, a second end, and a middle section;
wherein prior to mounting on catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible.

As has been previously explained, prior inflatable balloon structures have employed tubes or wraps of material that prior to mounting on a catheter shaft are either completely non-distensible or are completely distensible. In the case of completely distensible materials, these materials were rendered non-distensible on their ends only once they were anchored to the catheter shaft through some means, such as through use of a glue, tape wrap, heat welding, etc. Prior to the present invention, no one has taught or suggested that it might be in any way beneficial to render distensible balloon material non-distensible at its ends before the material is attached to a catheter shaft.

The Glickman patent is applied for the proposition that it teaches a balloon that once mounted on a catheter shaft could be removed to meet the limitations of the present application. Specifically, in the present Office Action it is argued that:

Glickman teaches all the claimed subject matter including a piece of tubing made out of elastomeric material (col. 16, lines 43-52), which is positioned on a catheter shaft to form a balloon which is slidable along the shaft while maintaining a "fluid tight seal" (claim 8). The fact that the ends of the balloon remain tight against the catheter shaft but are moveable along it, indicates that they are non-distensible as compared to the rest of the balloon, and that the balloon is a separate piece of

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equipment that maintains those properties of distensibility even when not mounted on a catheter.

Office Action of May 19, 2003, at 3.

In applicants' previous Response to Office Action of August 26, 2002, the differences between the Glickman patent and the present invention were explained at length. With regard to the above rejection, applicants explained that the structure taught by Glickman cannot meet the restrictions of the present claims because (1) the structure does not exist until after the balloon has been mounted on the catheter shaft, and (2) the slidable balloon cannot be removed from the catheter shaft without destroying the catheter shaft and/or balloon in the process. Response to Office Action of August 25, 2002, at 5-6. Both of these conclusions are based on the presence of "stops" (180, 181) that Glickman mounts on the catheter shaft within the balloon. These stops require that the balloon be constructed *in situ* on the catheter shaft (that is, since the stops must be within the balloon to function in accordance with the Glickman disclosure, there is no way to form the balloon off of the catheter shaft and then later mount it on the catheter shaft on either side of the stops). Moreover, once mounted on the catheter shaft on either side of the stops, there is no way to separate the slidable balloon from the catheter shaft without destroying the catheter shaft in the process (that is, the stops define "maximum" and "minimum" sliding distances for the balloon along the shaft and the stops mounted within the balloon prevent the balloon from being slid in either direction beyond the stops and off of the catheter shaft).

These arguments are summarily dismissed in the present Office Action under the premise that "the stops are an *optional* feature." Office Action of May 19, 2003, at 6 (emphasis in original). It is asserted:

Applicant argued that Glickman requires the stops within the balloon to prevent the balloon from being slid off the catheter (or being slid onto the catheter prior to rendering the ends non-distensible). However, figure 8 (not 8A or 8B) shows a slidable balloon without the stops. The stops are an *optional* feature.

Id.

The Glickman patent contains no suggestion that the stops within its balloon are in any way "optional." First, Glickman's description of his drawings make it clear that Figures 8a, 8b, and 8c are detailed views of the wide-angle view of the Figure 8 relied upon in the present Office Action. Specifically, the patent describes each of Figures 8a, 8b, and 8c as being "...an exploded cutaway cross-sectional side view of the interior of the slidable balloon of FIG. 8" Col. 14, lines 9-21.

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Thus, Figure 8 cannot be divorced from Figures 8a, 8b, and 8c with respect to their relative disclosures.

The stops are plainly shown in each of Figures 8a, 8b, and 8c, and Glickman devotes several paragraphs to explaining how these stops define the "maximum spacing" and "minimum spacing" of the movement of the slidable balloon along the catheter shaft. Col. 17, lines 17-34. Although the stops cannot be seen in Figure 8 as presented (perhaps because of oversight by the draftsman or because the stops were deemed too small to be properly presented in that wide-angle view), their presence in Figures 8a, 8b, and 8c make it clear that Glickman intended them to be in the embodiment illustrated in Figure 8.

In fact, the presence of these stops is so critical to Glickman's invention, that they are required elements in every one of Glickman's claims. Independent claim 1 requires the presence of "a first stop" and "a second stop" within a slidable ("second") balloon. Col. 19, lines 41-52. Similarly, independent claim 10 also requires "a first stop" and "a second stop" within the slidable balloon. Col. 20, lines 42-52.

It is important to note that the Glickman patent is directed to providing an apparatus for carefully controlling the delivery of highly toxic substances to targeted treatment sites within a patient (see, e.g., col. 1, lines 4-9 ("The instant invention provides a novel apparatus and process of perfusing a high concentration of a chemotherapeutic agent through a tumor occurring in an isolated portion of a patient, without contaminating the blood circulating in the substantial remainder of the patient's blood circulatory system outside of the isolated portion, with the agent.")). In light of this intent, Glickman goes to great lengths to emphasize that his invention requires isolation of the treatment area (see, e.g., col. 12, lines 31, 40, 46, 51, 56, 63; col. 13, lines 46-47), and critical sizing and spacing of the treatment area (see, e.g., col. 14, lines 47-48; col. 17, lines 35-45). Glickman specifically teaches that "...common to all of the double balloon catheter embodiments of the instant invention is the critical 'customized' sizing and spacing of the respective elements thereof, in accommodation to the varied sizes and dimensions of: the particular tumor to be treated, and the blood vessel which withdraws the blood therefrom, and in particular the adjustable spacing between the two balloons which is enabled by the slidable balloon." Col. 17, lines 38-45 (emphasis added).

In light of the intended use of the Glickman device, it is plain that the stops within his slidable balloon are in no way "optional." Glickman makes it clear that the slidable balloon must be carefully positioned between the minimum and maximum spacing distances enabled by the stops.

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Separation of the slidable balloon from the catheter shaft is certainly not an option since the continued presence of that balloon on the catheter shaft is critical to preventing the contamination of systemic blood with toxic chemotherapeutic agents.

For the foregoing reasons, the stops within the balloon taught by the Glickman patent are critical elements of its disclosure. The Glickman patent will not function as intended without the stops, and, as applicants had previously explained, the presence of the stops on the catheter shaft fundamentally distinguishes that reference from the invention taught and claimed in the present application.

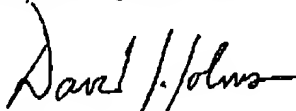
Amendments

The above amendments to claims 28 and 36 are those suggested by the Examiner in the present Office Action. Office Action of May 19, 2003, at 6. Claims 29 and 37 have also been amended to better distinguish the structure of the balloons defined therein over the process used to make such balloons. Support for these amendments is found in the application as filed, such as at page 6, lines 28-32, and page 7, lines 3-4. With these amendments, all formal objections to the present application have been addressed.

Conclusion

Applicants respectfully request reconsideration of the present rejection in light of this further analysis of the Glickman patent. Withdrawal of the final rejection and allowance of the present application are respectfully requested. If any questions remain, applicants request a phone interview before the next action.

Respectfully submitted,



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